

Attachment C**EVALUATION CRITERIA FOR SUBSTANCES ADDED TO OR REMOVED FROM THE NATIONAL LIST****Category 1. Adverse impacts on humans or the environment?**Substance Milk Replacers

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]			X	
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]			X	
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		TAP
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			X	
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]			X	
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			X	
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		TAP
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		TAP
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		TAP
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]			X	
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			X	
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]			X	
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			X	

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 2. Is the Substance Essential for Organic Production?

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Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]		X		TAP
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		X		TAP
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		TAP
4. Is there a natural source of the substance? [§205.600 b.1]	X			Most organic dairy producers use whole organic milk when circumstances require a milk replacer for calves.
5. Is there an organic substitute? [§205.600 b.1]	X			Most organic dairy producers use whole organic milk when circumstances require a milk replacer for calves.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			Most organic dairy producers use whole organic milk when circumstances require a milk replacer for calves.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
9. Is there any alternative substances? [§6518 m.6]	X			Most organic dairy producers use whole organic milk when circumstances require a milk replacer for calves.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Most organic dairy producers use whole organic milk when circumstances require a milk replacer for calves.

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 3. Is the substance compatible with organic production practices?

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Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]	X			TAP
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	X			TAP
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X			TAP
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]			X	
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			X	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:			X	
a. copper and sulfur compounds;				
b. toxins derived from bacteria;			X	
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	
d. livestock parasiticides and medicines?			X	
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			X	

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